

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.

Serial No.: 09/873,899

Filed: June 4, 2001

For: *MIXTURES OF INSULIN DRUG-OLIGOMER CONJUGATES COMPRISING
POLYALKYLENE GLYCOL, USES THEREOF,
AND METHODS OF MAKING*

-CONFIDENTIAL-

**Declaration of Balasingam Radhakrishnan, Ph.D.
Under 37 C.F.R. § 1.131 and *In re Katz*¹**

Sir:

I, Balasingam Radhakrishnan, Ph.D. hereby declare as follows:

1. I am the Director of Chemistry Development and Manufacturing at Nobex Corporation located in Research Triangle Park, N.C.
2. I am a named co-inventor on U.S. Patent Application Serial No. 09/873,899 entitled, "Mixtures of Insulin Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making" (*hereinafter*, "the '899 application"), filed June 4, 2001.
3. The subject matter of the application was invented by Nnochiri N. Ekwuribe, Christopher H. Price, Aslam M. Ansari, and myself. Each of us is named as an inventor on the '899 application.
4. Radhakrishnan et al. Stability and Physical Characteristics of Orally Active Amphiphilic Human Insulin Analog, Methoxy (Polyethylene Glycol) Hexanoyl Human Recombinant Insulin (HIM2). The 27th International Symposium on Controlled Release of Bioactive Materials and the Third Consumer and Diversified Products Conference, July 7-13, 2000, was co-authored by one of the inventors of the

¹ 687 F.2d 450, 215 U.S.P.Q. 14 (C.C.P.A. 1982).

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above-captioned patent application, Balasingam Radhakrishnan, and two additional authors: J.S. Rajagopalan and J. Burnham.

5. Some of the experiments described in the Radhakrishnan et al. reference were conducted by J.S. Rajagopalan and J. Burnham. These experiments were under the direction and supervision of Nnochiri N. Ekwuribe, Christopher H. Price, Aslam M. Ansari, and myself.
6. The authors named on the Radhakrishnan et al. reference who are not included as inventors on the above-captioned patent application did not contribute to the conception of the claimed invention set forth in the above-captioned patent application.
7. For the reasons set forth above, the inventors named on the above-captioned patent application are the true inventors thereof.
8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Balasingam Radhakrishnan
Balasingam Radhakrishnan, Ph.D.

04 / 03 / 03
Date

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